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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,662	09/23/2003	David James Johnson	MED-001139 C2	1064

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EXAMINER	
LEWIS, KIANDRA CHARLE	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,662	JOHNSON, DAVID JAMES	
	Examiner	Art Unit	
	Kiandra C. Lewis	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 35-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,638,270 and in view of claims 1,10,11, and 14 of Patent No. 6,471,685. The key element that claim 35 recites and is not found explicitly in claim 1-6 of ('270) is that the input and out connectors are hermetically sealed wit a conduit. Claims 10,11,and 14 of patent ('685) teaches that it is known to arrange the inlet and exhaust conduits to a wound dressing to be hermetically sealed wit a conduit. It would have been obvious to have modified claims 1-6 of US Patent ('270) to have provided the inlet and exhaust conduits with the

capability to be hermetically sealed as taught in claims 1,10,11, and 14 of US Patent ('685) for the purpose of preventing potential harmful contamination of the wound.

3. As to claim 36 of the application wherein the further limitation recites "having at least one patient engaging base member includes the step of providing at least one patient engaging base member having the bottom surface" (see lines 5-6 of claim 1 of the patent '270).

4. As to claim 37 it recites "providing a cover member comprising a substantially non-flexible material, to, in turn, substantially maintain the defined volume substantially constant" (see claim 2 of the patent '270).

5. As to claim 38 it recites "providing a cover member comprising a substantially flexible material, to, in turn, facilitate fluctuation of the defined volume" (see claim 3 of the patent '270).

6. Claim 38 recites "included the step of providing a total cross-sectional area of the at least one input connector which is greater than the total cross-sectional area of the at least on output connector" (see claim 4 of the patent '270).

7. Claim 40 recites "includes the step of providing at least one input connector and at least on exhaust connector which are substantially identical" (see claim 5 of the patent '270).

8. Claim 41 recites "includes the step of providing a plurality of input connectors" (see claim 6 of the patent '270). See also claim 11 of patent '685.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Henley et al. (U.S. Patent No. 6,458,109).

11. As to claim 35 Henley teaches a medical dressing **10** that includes

an isolating member with at least one patient engaging base member **Fig 4 col. 10 lines 56-60**

the cover member along with the affected area of the patient substantially defining a volume **Fig. 1,**

at least one input connector capable of substantially hermetic sealing with a conduit **22,**

at least one exhaust connector capable of substantially hermetic sealing with a conduit **24,**

operatively securing the isolating member onto the patient so that at least a portion of the affected area of the patient is isolated from an external environment **Fig. 1,**

controllably inputting matter **15** into the volume through the at least one input connector **22**

controllably exhausting matter from the volume through the at least one exhaust connector **24**

controlling the flow and pressure of fluid directed into and out of the isolating means to in turn provide a localized hyperbaric treatment **col. 7 lines 9-28, col. 7 lines 37-42**.

12. As to claim 36, Henley clearly discloses that the patient engaging member has a bottom surface **Fig. 4, Fig 9**.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (U.S. Patent No. 6,458,109) in view of Stivala (U.S. Patent No. 4,224,941).

15. As to claim 37 Henley et al. disclose all the limitation of the base claim but does not explicitly state that the cover member is made of a non-flexible material to maintain the defined volume constant. Stivala teaches the used of a hyperbaric treatment device that has a cover member **15** and when inflated maintains a constant volume (**col. 3 lines 45-50**). The art of Henley et al. and Stivala are analogous because they are from the similar problem solving area of treating wounds. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of

Henley et al. with that of Stivala for the purpose of providing a patient user with a standardized treatment of a burn or wound that will remain constant.

16. Claims 38, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al (U.S. Patent No. 6,458,109) in view of Westwood (U.S. Patent No. 5,810,795).

17. As to claim 38 Henley discloses all of the limitations of the base claim as stated in the prior in the rejection of claim 35 however Henley et al. do not explicitly state that the cover member is a flexible material that in turn facilitates the fluctuation of the defined volume. However Westwood discloses a hyperbaric device in which the cover member is made of flexible material **col. 4 lines 25-29, lines 42-46, col. 5 lines 10-14**. Henley and Westwood are analogous art because they are from the same field of endeavor of treating an area of the body or skin with hyperbaric treatment to enhance wound healing. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use a flexible cover as taught in Westwood in the invention of Henley. The motivation would have been so that the pressure of the device could be easily adjusted **col. 4, lines 64-67**. Therefore, it would have been obvious to combine Westwood with Henley to obtain the invention as specified in claim 38.

18. As to claim 39 Henley et al. disclose all the limitations of the base claim as stated in the above rejection. However Henley et al. do not disclose a step of providing a total cross-sectional area of the at least one input connector which is greater than the total cross-sectional area of the at least one output connector. Westwood discloses that his

device has two input connectors **15,19** and one output connector **17**. If there are two inputs of Westwood and one output then the total cross sectional area of **15** and **19** combined could be greater than that of the output **17**. At the time of the invention it would have been obvious to a person of ordinary skill in the art to configure the device of Henley et al. as disclosed by Westwood with an increased cross-sectional area of the inputs for the purpose of providing greater amount of medicinal fluids or gases to the treatment area.

19. As to claim 40, Henley et al. disclose all of the limitations of the base claim. Westwood teaches the use of multiple input connectors and does not state that they are identical. At the time of the invention it would have been obvious for the input connectors and exhaust connector to be identical for the purpose of having a standardized regulation of flow and pressure of the wound area. Likewise the connectors could be of different sizes for the purpose of varying the flow and pressure of the wound area. The applicant has not disclosed any criticality to these claimed features stating why it is pertinent for these connectors to be identical versus being of different size. It is not evident that this specific feature serves a specific purpose or solves a specified problem. Therefore it is considered an obvious matter of design choice for the connectors to be identical or to be of any configuration, shape, or size and the device would still perform with a satisfactory performance

20. As to claim 41 is it rejected upon the same basis as stated in the prior rejection of claim 39. In the modification of Henley in view of Westwood, Westwood teaches the use of a plurality of input connectors **15,19**. It would have been obvious to one having

ordinary skill at the time of the invention to provide more than one input device for the purpose of providing greater amount of medicinal treatment to the affected area or for the purpose for providing a variety of different medicaments or gases to the affected area (**col. 6 lines 37-42**).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kiandra C. Lewis whose telephone number is 571-272-7517. The examiner can normally be reached on Mon-Thurs 9AM-6PM and alternating Fridays 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCL